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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,728	01/29/2004	Moises Calderon		7953

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EXAMINER	
ALEXANDER, JOHN D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,728	CALDERON, MOISES	
	Examiner	Art Unit	
	John D. Alexander	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006, Response to 1st Non-Final*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 4 is objected to because of the following informality: the element "a peristaltic pump connected to the shunt tubing" at the end of the claim is numbered as sub-element "iii" under element "b." Written this way, the pump is claimed as being sealed inside the container. It is suggested that "*iii.* a peristaltic pump *connected to*..." be changed to --*c.* a peristaltic pump *for connection* to...--.

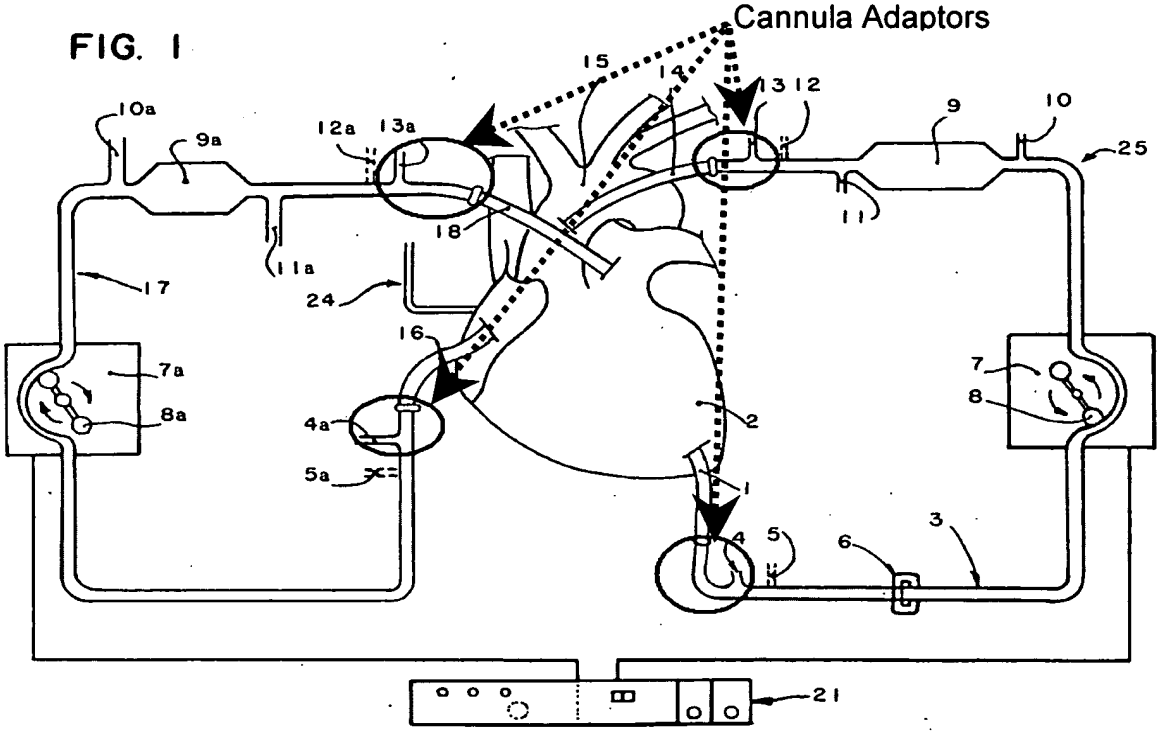
Claim Rejections - 35 USC § 103

Claims 1, 2, 13, 14, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. (Patent No. 4662355) in view of Leschinsky et al. (Patent No. 5439448).

- Regarding **Claims 1, 13, and 20**, Pieronne et al. disclose a system and method for pump-assisted myocardial revascularization without cardiopulmonary bypass comprising: surgically attaching a first cannula to the aorta (Fig. 1, element 14; Col. 2, lines 60-62); surgically attaching a second cannula the left atrium (Fig. 1, elements 1; Col. 2, lines 41-43); interconnecting the first and second cannulae with a first atrial-arterial shunt comprising a section of tubing having first and second ends and an interior (Fig. 1, element 3; Col. 2, lines 44-46); priming the shunt to remove air (Fig. 1, elements 4, 6, and 13; Col. 2, lines 47-48 & 66; Col. 3, lines 12-17); inserting the shunt tubing into a first peristaltic pump (Fig. 1, elements 7 & 8); and activating the pump to pump blood through the shunt and in parallel with the patient's heart pumping action (Col. 1, lines 6-11; Col. 7, lines 52-58). Regarding first and second cannula adapters, each with a vent for priming, see the Pieronne et al. Fig. 1 on the following page where examiner has marked the structure considered to meet these claim requirements. Here, examiner considers that the

Pieronne et al.' air purges (i.e. vents for priming purposes) inherently include a sealing means for selectively opening and closing the vents. Without such a sealing means, the vents would create deleterious open holes in the blood circuit.

FIG. 1



Regarding the limitation of Claim 13 that the "first peristaltic pump is one of a medical facility's existing peristaltic pumps from a cardiopulmonary bypass machine," the pump of Pieronne et al. is obviously a medical facility's existing pump and is disclosed as the type conventionally used for extra-corporeal circulation (Col. 2, lines 50-54). Pieronne et al. do not explicitly disclose that the section of tubing is translucent. Leschinsky et al. disclose a method and apparatus for interconnecting blood-carrying tubing, cannulae, and/or external pumps and provide a teaching that blood-carrying tubing is most preferably formed of a clear material (Col. 6, lines 5-7). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Leschinsky et al. to modify the tubing of Pieronne et al. to be translucent.

The motivation would have been to enable the clinician to view the interior of the tubing to detect bubbles or other contaminants (Col. 6, lines 5-9).

- Regarding **Claim 2**, as related above, it seems that the vents of Pieronne et al. inherently include a sealing means. However, Pieronne et al. do not explicitly disclose a cap removably attached to each vent. The system and method of Leschinsky et al. further includes vents for removing air from the a blood-carrying circuit, wherein the vents include removably attached caps for selectively opening and closing the vents during priming (Fig. 5, elements 28 & 32; Figs. 8, 9, & 10, elements 128 & 132; Col. 7, lines 39-55; Col. 9, lines 16-57). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Leschinsky et al. to modify the priming vents of Pieronne et al. to include removably attached caps. The motivation would have been to provide an easy, well-known means for closing the vents during normal pumping and for opening them during priming to allow air bubbles to escape to the external environment.
- Regarding **Claim 14**, it seems inherent from Pieronne et al.'s description of the vents (Fig. 1, elements 4 & 13) as "air purges" that the vents are opened at appropriate times to allow the passing flow of blood to force out (i.e. purge) any trapped air.

Claims 3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. as applied to claims 1 and 13 above, and further in view of Aboul-Hosn et al. (Patent No. 6935344). Pieronne et al. do not explicitly disclose that the pump is placed within one meter of the patient or that the tubing is no longer than two meters. Aboul-Hosn et al. disclose systems and methods for left and right side heart assistance including the use of shunt tubing and peristaltic pumps (Fig. 5; Col. 18, lines 41-54).

Additionally, Aboul-Hosn et al. teach that it is important to bring the pump as close to the patient as possible and to minimize priming volume, the volume of the support system that is external to the patient (Col. 5, lines 2-16; Col. 17, lines 15-26). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Aboul-Hosn et al. to modify the heart support system of Pieronne et al. to include placement of the pump within one meter of the patient and to utilize tubing that is no longer than two meters. The motivation would have been to provide well-known advantages of minimizing the distance and time that blood travels outside the body, such as preventing the occurrence of hemolysis and eliminating the necessity of cooling or warming the blood (Col. 17, lines 24-39).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. as applied to claim 13 above, and further in view of Runge (Patent No. 5743845). As related above, Pieronne et al. disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Pieronne et al. further disclose simultaneous right side assistance that utilizes right side cannulation sites and a second atrial-arterial shunt and peristaltic pump (Fig. 1, elements 4a, 7a, 8a, 13a, & 16-18; Col. 2, lines 66-68; Col. 3, lines 1-11). Pieronne et al. disclose that the third cannula is surgically attached to the pulmonary artery, but do not explicitly disclose that the fourth cannula is attached to the right atrium. Instead the fourth cannula is described as attached to "the outlet of the organ, such as the vena cava." Runge discloses a system and method for left and right side heart support that omits the need for an oxygenator of a conventional cardiopulmonary bypass system (Figs. 4 & 5; Col. 3, lines 24-27). Runge further provides a teaching that the cannulation sites most preferred by surgeons "will be from the right atrium to the pulmonary artery, and from the left atrium to the

aorta" (Col. 3, lines 9-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Runge to modify the heart support system of Pieronne et al. to include attaching the fourth cannula to the right atrium. The motivation would have been to provide the cannulation configuration most preferred by surgeons.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and Runge as applied to Claim 16 above, and further in view of Aboul-Hosn et al. Comments made above in rejection of Claims 3 and 15 regarding tubing length and placement of the pump within one meter of the patient apply here as well.

Claims 4-6, 8, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and further in view of Rawles et al. (Patent No. 6890316). Pieronne et al. do not explicitly disclose that the above-described atrial-arterial shunts are packaged in a sealed, openable container having a sterile interior. Regarding all other elements of these claims, comments made above in rejection of Claims 1, 2 and 13 apply here as well. Rawles et al. disclose a tubing set for a blood handling system that includes placing the tubing in a sealed, openable container having a sterile interior (Fig. 5, elements 60 & 65). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Rawles et al. to modify the heart support system of Pieronne et al. to include such sterilized packaging of the shunt prior to its use in the pumping system. The motivation would have been to prevent contamination of the tubing, and possible subsequent contamination of the patient's blood, while handling it before connection to the cannulae.

Claims 7, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and Rawles et al. as applied to Claims 4-6, 8, 9, and

11 above, and further in view of Aboul-Hosn et al. Comments made above in rejection of Claims 3 and 15 regarding tubing that is no longer than two meters apply here as well.

Response to Remarks

Regarding independent Claim 1 as previously rejected under 35 U.S.C. 103(a) as being unpatentable over Utterburg in view of Leschinsky et al. and independent Claim 4 as previously rejected under 35 U.S.C. 103(a) as being unpatentable over Utterburg in view of Leschinsky et al. and Rawles et al., Applicant's remarks have been considered but are moot in view of the new grounds of rejection. However, examiner notes that Applicant has successfully given patentable weight to the preamble elements of these claims. Additionally, it is noted that Applicant has given weight to the functional description of the vent structure via the use of means-plus-function language under 35 U.S.C. 112 6th Paragraph.

Regarding dependent Claims 6-12 and independent Claim 13, examiner's previous indication of allowability is withdrawn in view of further search and consideration of the prior art. These claims are now rejected under the new grounds related above in this Office Action. Examiner respectfully apologizes for the previous, seemingly erroneous indication of allowable subject matter.

Conclusion

Because the new grounds of rejection presented in this office action were *not* necessitated by Applicant's amendment, this action is **NON-Final**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA

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4/20/06